DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 26 2000

Mr. Robert S. Milanese
President
National Association of Pharmaceutical
Manufacturers
3279 Veterans Memorial Highway
Suite D-7
Ronkonkoma, New York 11779

Re: Docket No. 99P-4618/CP1

Dear Mr. Milanese:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated October 26, 1999. You request that the FDA continue to review and approve suitability petitions seeking a change in strength, dosage form, active ingredient, or route of administration without applying the regulatory requirement that applications for changes in dosage form, active ingredient, or route of administration contain a pediatric assessment (21 CFR 314.55).

FDA has been unable to reach a decision on your petition because it raises significant and complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

99P-4618

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